Transcatheter Mitral Valve Therapies: New Advances in Techniques and Devices

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NorthShore University HealthSystem
Evanston Hospital

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Disclosure Information

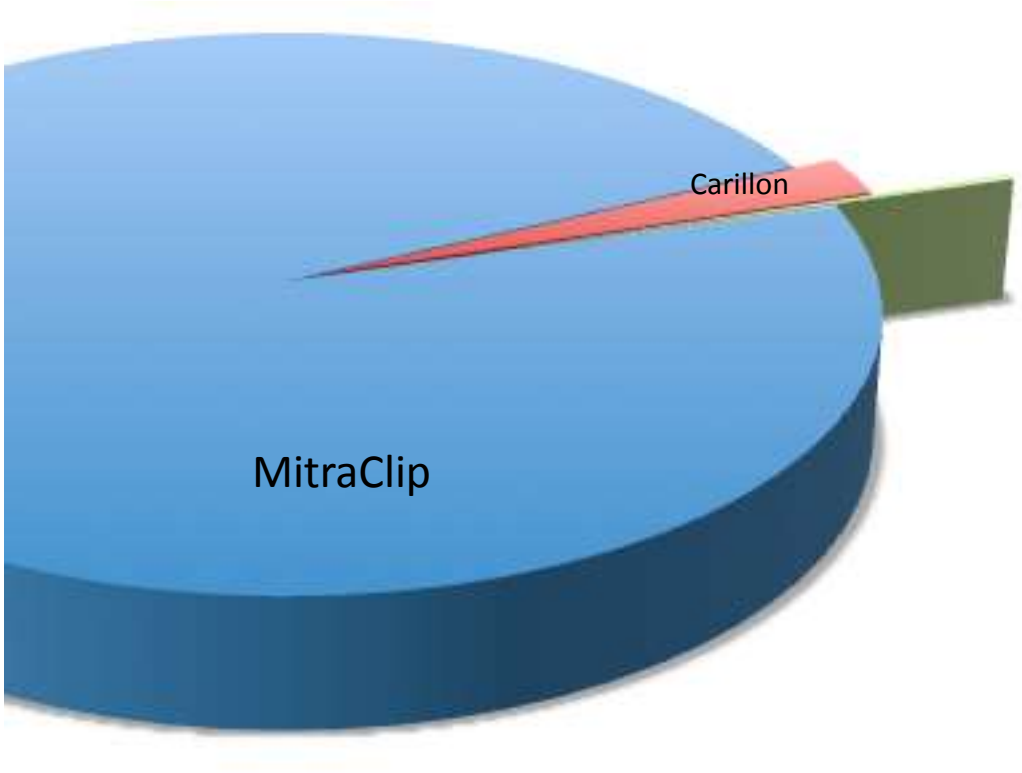
The following relationships exist:

Grant support: Abbott, BSC, Edwards, WL Gore
Consultant: Abbott, BSC, Coherex, Edwards, JenaValve, Diiachi Sankyo-Lilly, WL Gore

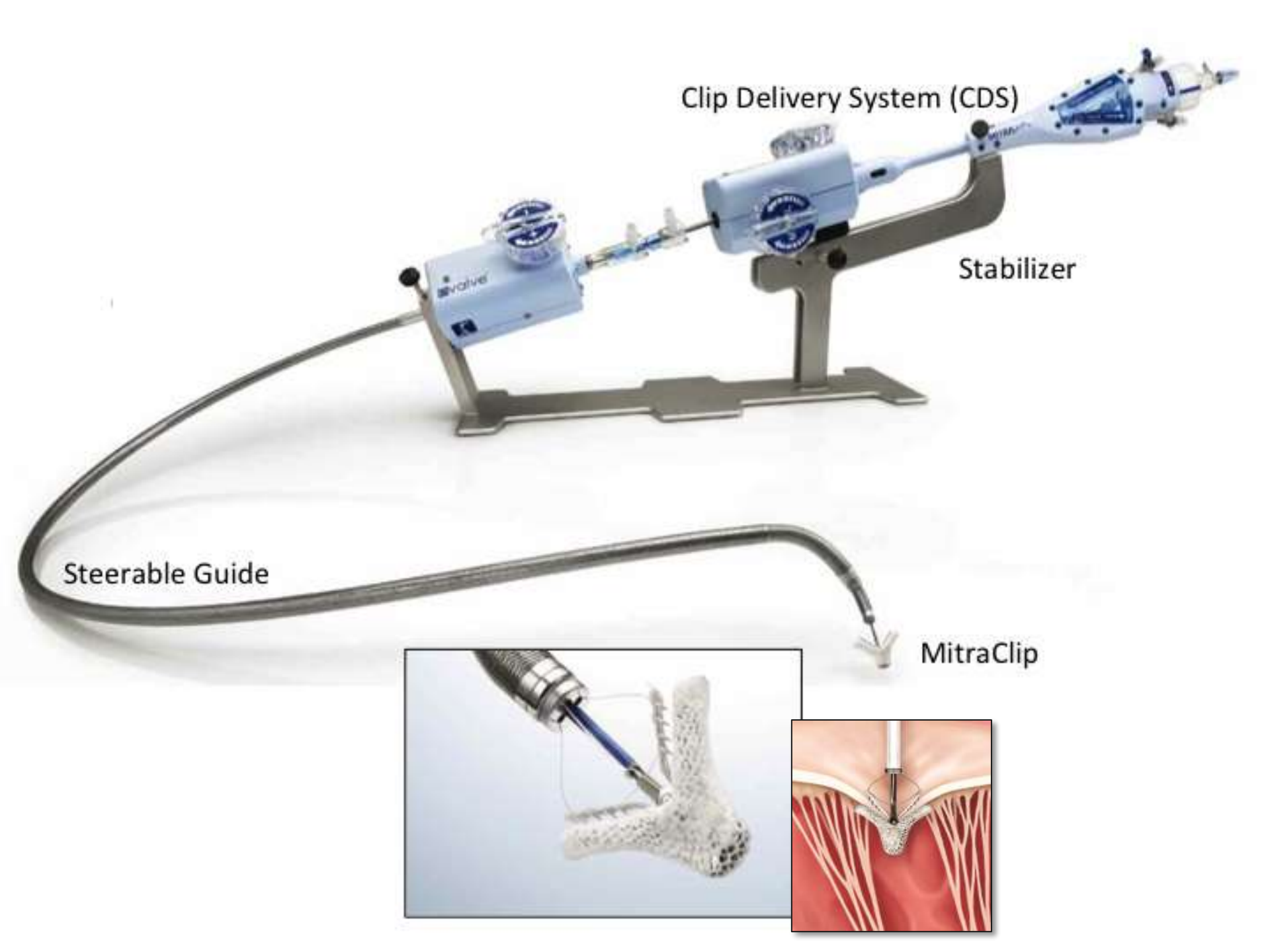
Off label use of products and investigational devices will be discussed in this presentation

Percutaneous Mitral Therapy

Treated Patients



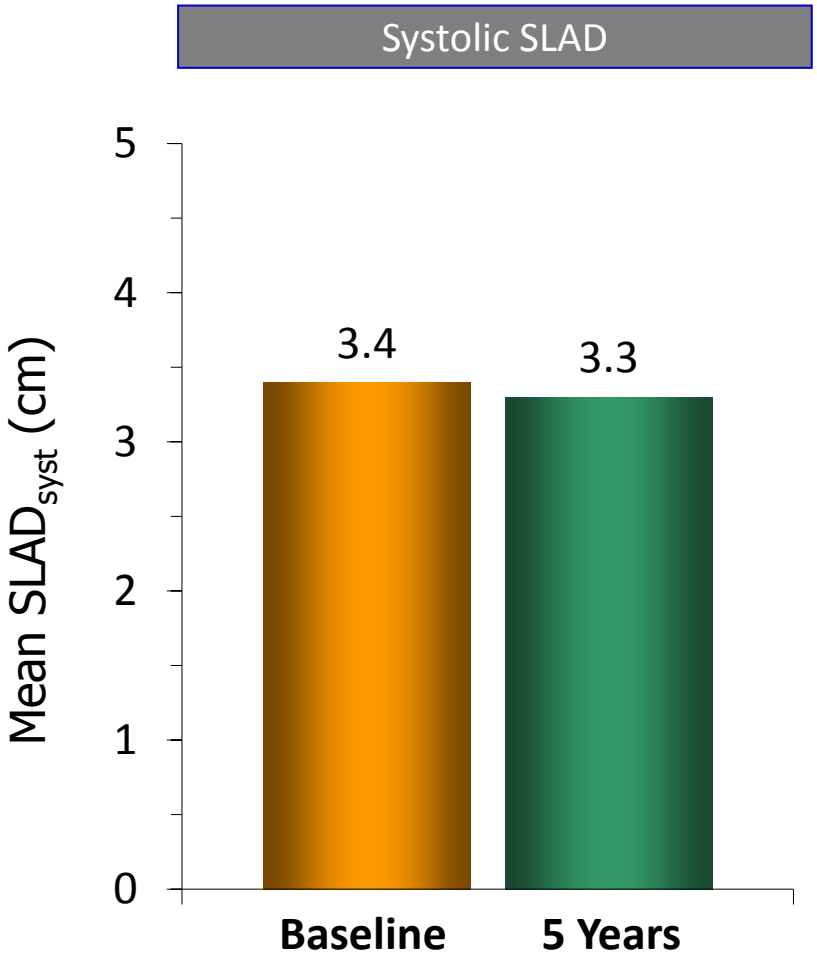
MitraClip	>19,000
Carillon	>300
Mitralign	>60
Cardioband	>40
Replacement	>25

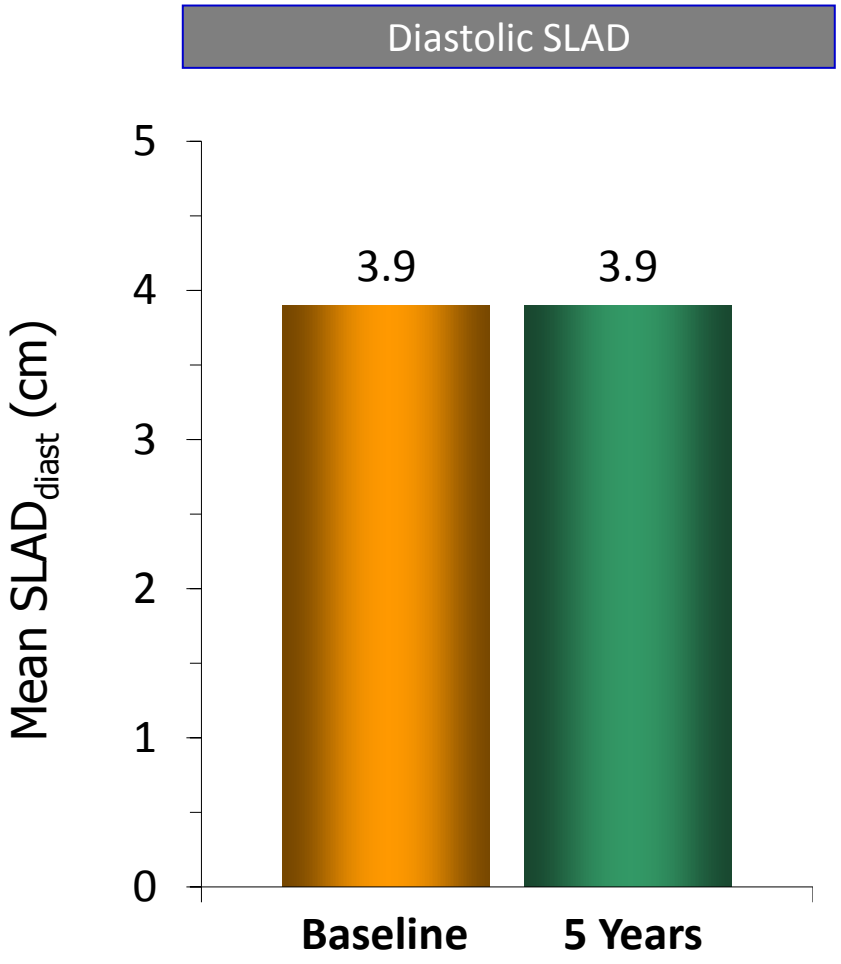

Clip Delivery System (CDS)
Stabilizer
Steerable Guide
MitraClip

The EVEREST II Randomized Clinical Trial: 5 Year Outcomes By MR Etiology

Septal Lateral Annular Dimensions

EVEREST II RCT All Treated Patients - MitraClip Group (N=178)





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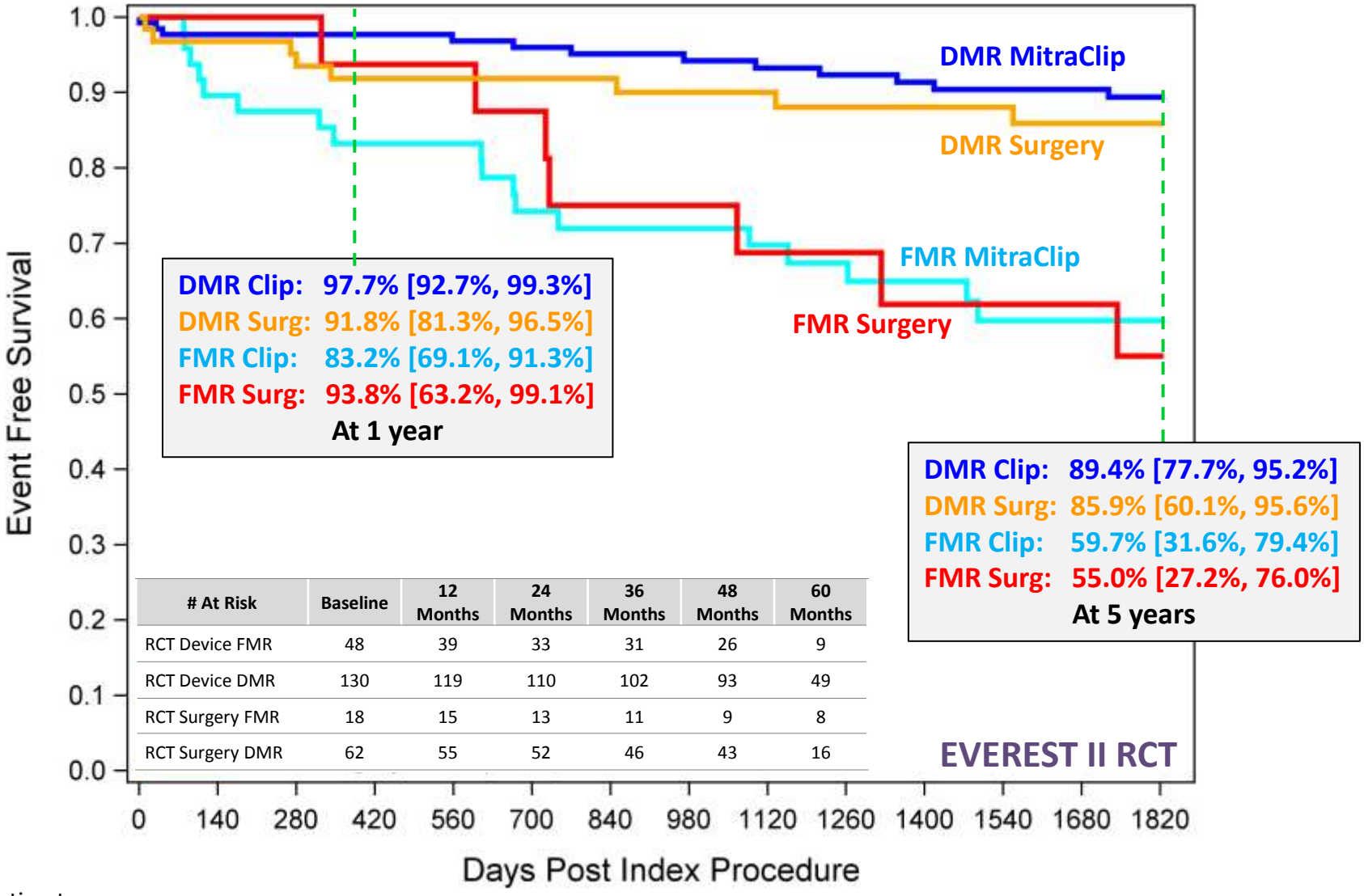
Freedom From Mortality & Reintervention



# At Risk	Baseline	12 Months	24 Months	36 Months	48 Months	60 Months
RCT Device FMR	48	39	33	31	26	9
RCT Device DMR	130	119	110	102	93	49
RCT Surgery FMR	18	15	13	11	9	8
RCT Surgery DMR	62	55	52	46	43	16

Kaplan-Meier estimate

Improved Functional Status and Quality of Life in Prohibitive Surgical Risk Patients With Degenerative Mitral Regurgitation After Transcatheter Mitral Valve Repair

D. Scott Lim, MD,* Matthew R. Reynolds, MD, MSc,†‡ Ted Feldman, MD,§ Saibal Kar, MD,‖
Howa
Paul G

METHODS A prohibitive-risk DMR cohort was identified by a multidisciplinary heart team that retrospectively evaluated high-risk DMR patients enrolled in the EVEREST (Endovascular Valve Edge-to-Edge Repair Study) II studies.

RESULTS A total of 141 high-risk DMR patients were consecutively enrolled; 127 of these patients were retrospectively identified as meeting the definition of *prohibitive risk* and had 1-year follow-up (median: 1.47 years) available. Patients were elderly (mean age: 82.4 years), severely symptomatic (87% New York Heart Association class III/IV), and at prohibitive surgical risk (STS score: 13.2 ± 7.3%). TMVR (MitraClip) was successfully performed in 95.3%; hospital stay was 2.9 ± 3.1 days. Major adverse events at 30 days included death in 6.3%, myocardial infarction in 0.8%, and stroke in 2.4%. Through 1 year, there were a total of 30 deaths (23.6%), with no survival difference between patients discharged with MR ≤1+ or MR 2+. At 1 year, the majority of surviving patients (82.9%) remained MR ≤2+ at 1 year, and 86.9% were in New York Heart Association functional class I or II. Left ventricular

CONCLUSIONS TMVR in prohibitive surgical risk patients is associated with safety and good clinical outcomes, including decreases in rehospitalization, functional improvements, and favorable ventricular remodeling, at 1 year. (Real World Expanded Multi-center Study of the MitraClip System [REALISM]; NCT01931956)

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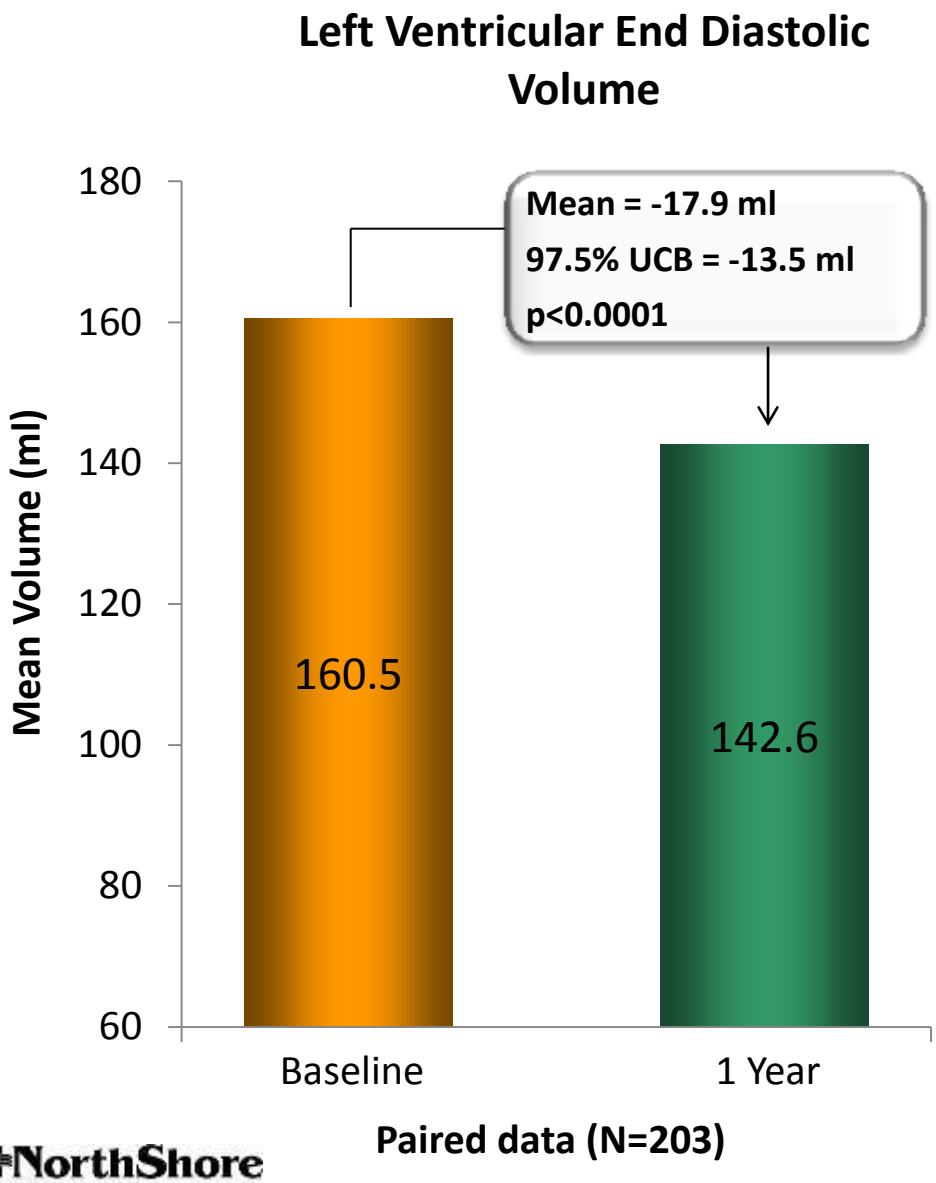
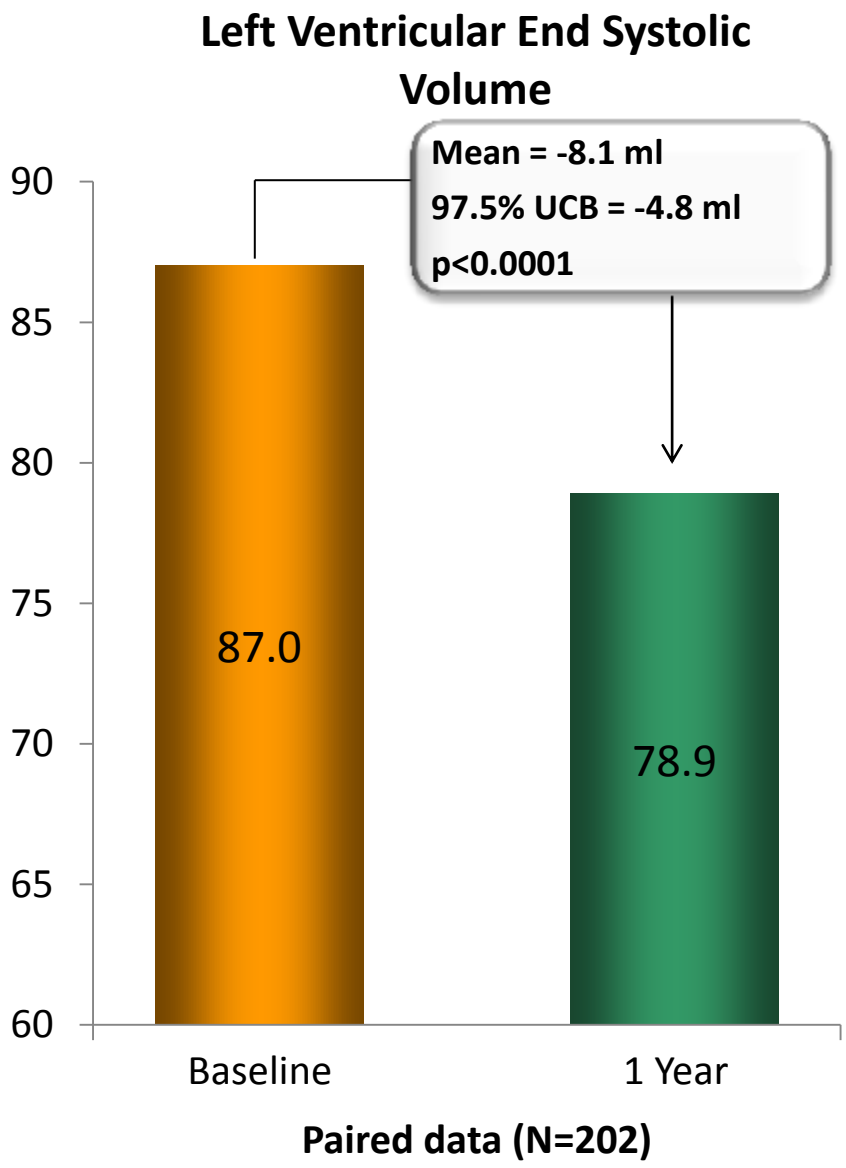
J Am Coll Cardiol 2014;64:182–92

Left Ventricular Volumes





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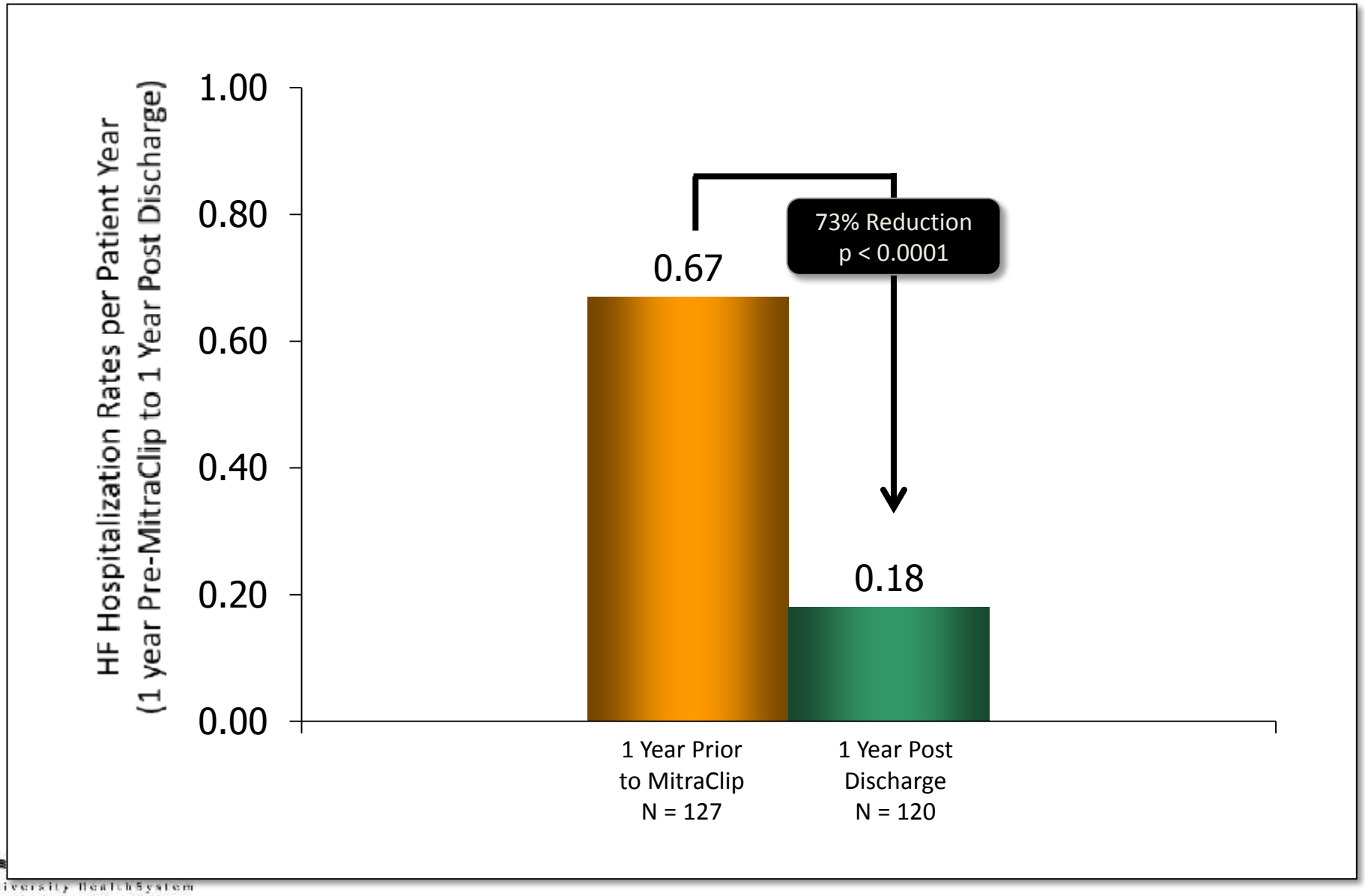
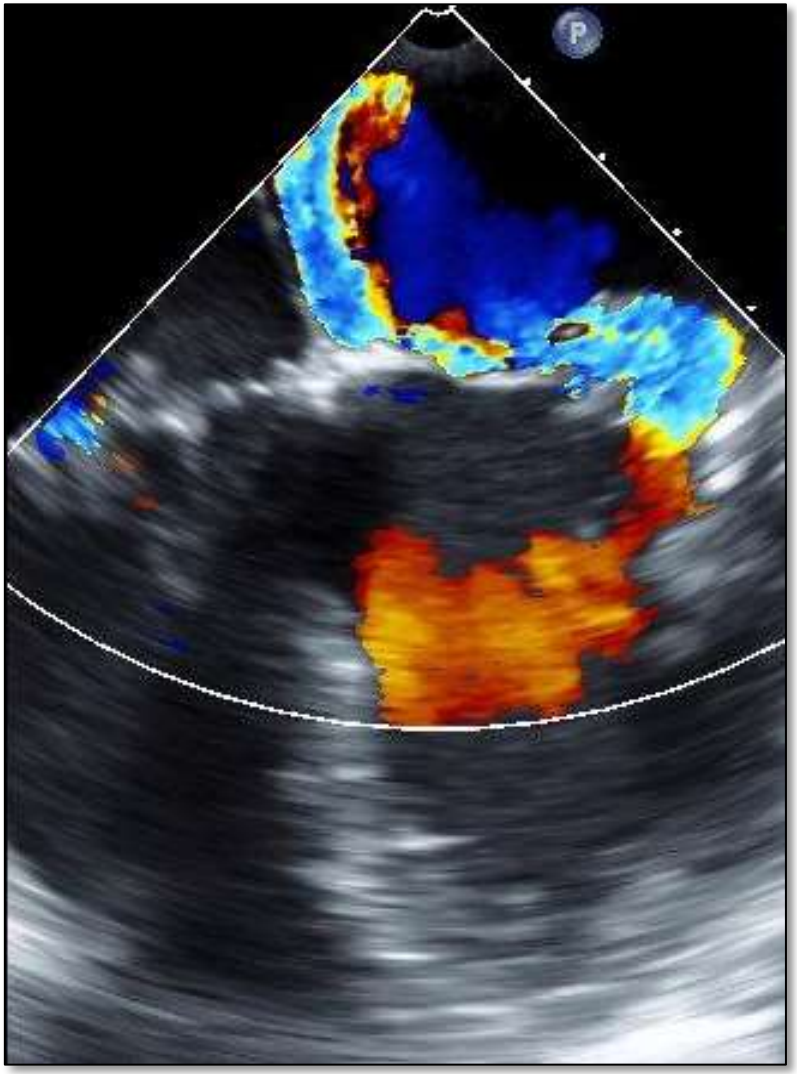
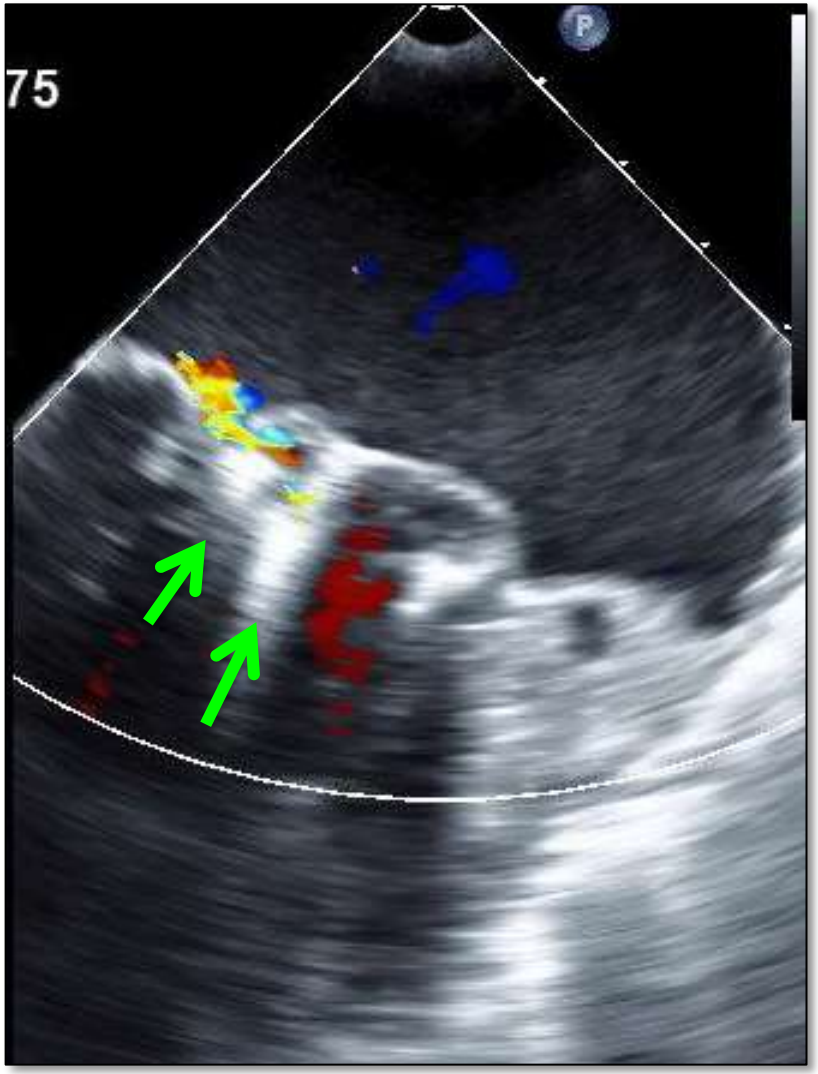
Hospitalizations For Heart Failure



Degenerative MR Case Example
Pre vs Post- 2 Clips





87M - Hospitalizations for CHF
EF 70% - PASP 50mmHg
STS - Repair 7.5% Replace 11%

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Therapy for MR

	Degenerative	**Functional**
Low Surgical Risk	Surgical Mitral Repair	?
High Surgical Risk	Commercial MitraClip	COAPT

Clinical Outcomes Assessment of the MitraClip Percutaneous Therapy for High Surgical Risk

COAPT TRIAL

~430 patients enrolled at up to 75 US sites

Significant FMR ≥3+ core lab; EF<50%; CHF hospitalization or BNP>300

High risk for mitral valve surgery- Local Heart Team

Specific valve anatomic criteria

Randomize 1:1

MitraClip

Control group Standard of care

Safety: Composite death, stroke, worsening renal function, LVAD implant, heart transplant at 12 months

Effectiveness: Recurrent heart failure hospitalizations

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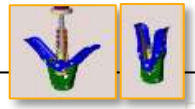
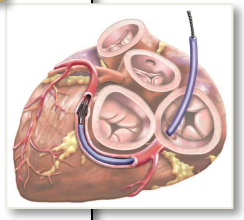
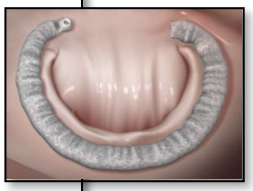
Percutaneous Mitral Repair Devices

Already gone

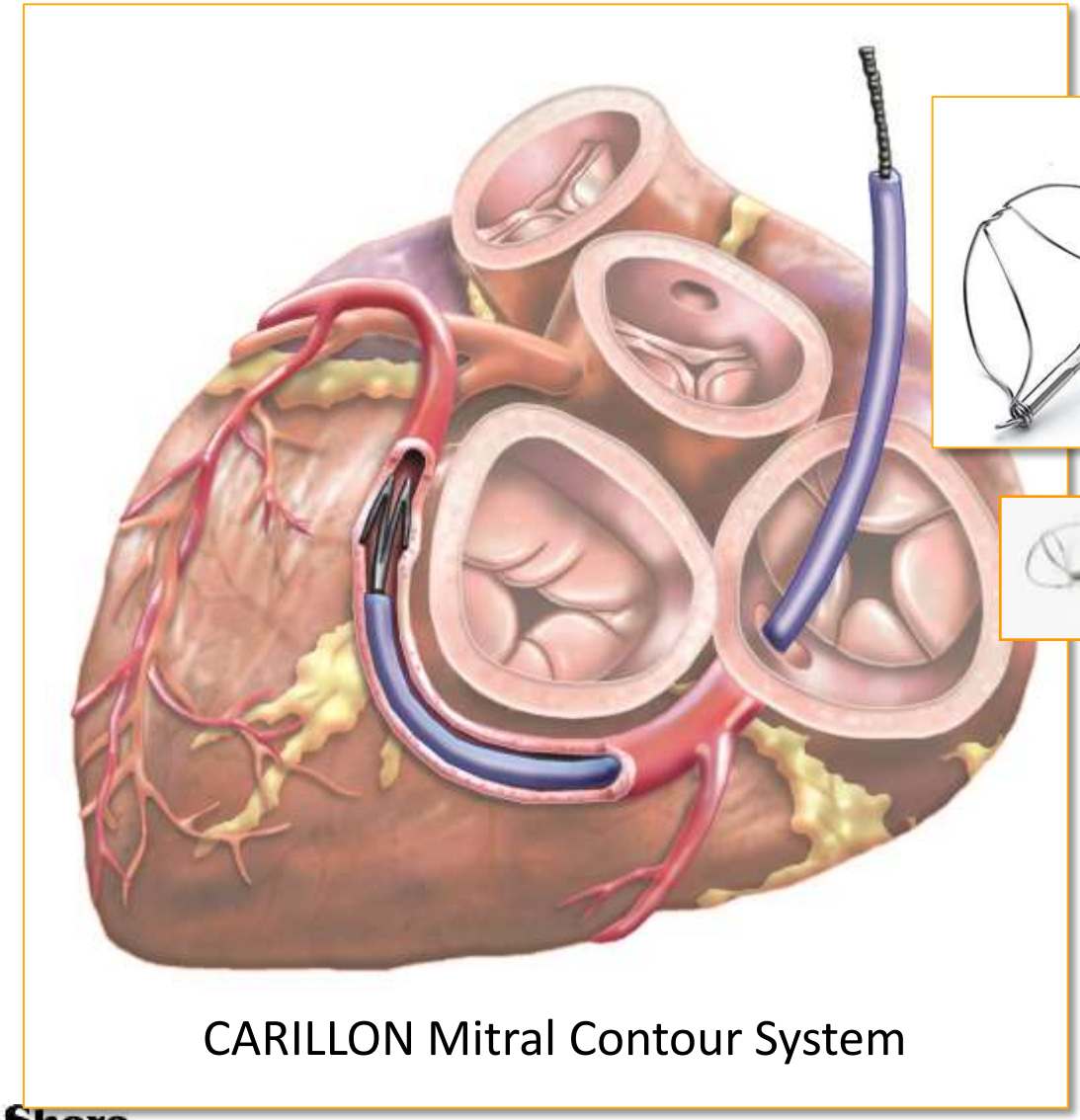
- PTMA
- Monarc
- Mobuis leaflet repair
- Recor RF annular remodeling
- Coapsys

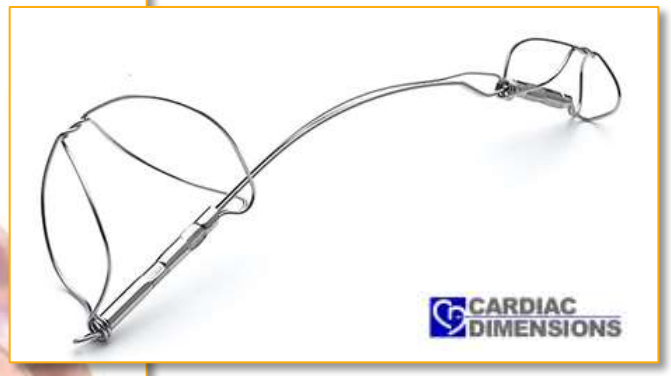
Still developing

- Leaflet repair
- CS annuloplasty
- Direct annuloplasty
- Cerclage
- Mitral spacer
- Midle Peak
- Chordal replacement
- Valve replacement

Coronary Sinus- Indirect Annuloplasty



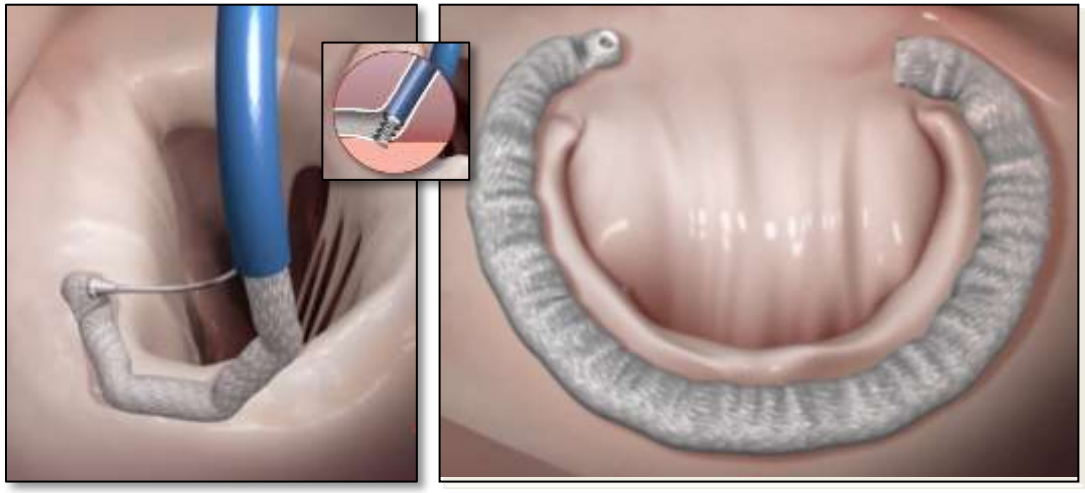


CARILLON Mitral Contour System

CARILLON Current Status

- REDUCE FMR
  - Randomized trial of Carillon versus sham
  - Europe and Australia
- CLINCH
  - Investigator driven pilot study of Carillon versus MitraClip
- Commercialized
  - Germany, Saudi Arabia, Turkey and expanding

Cardioband TRANS FEMORAL



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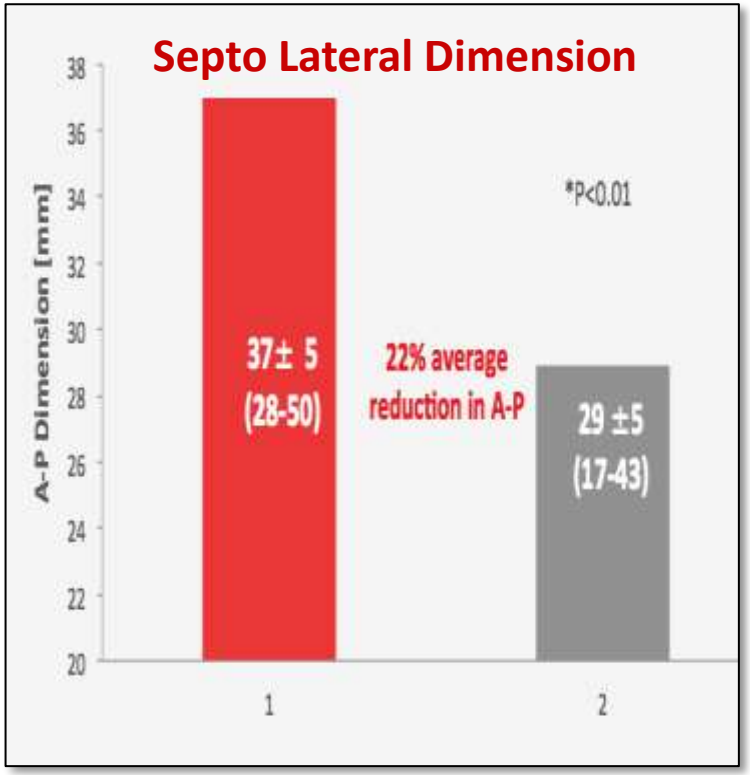
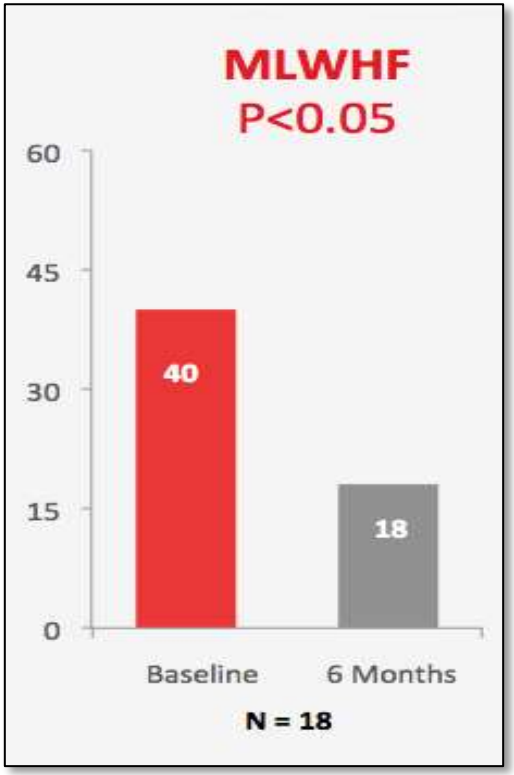
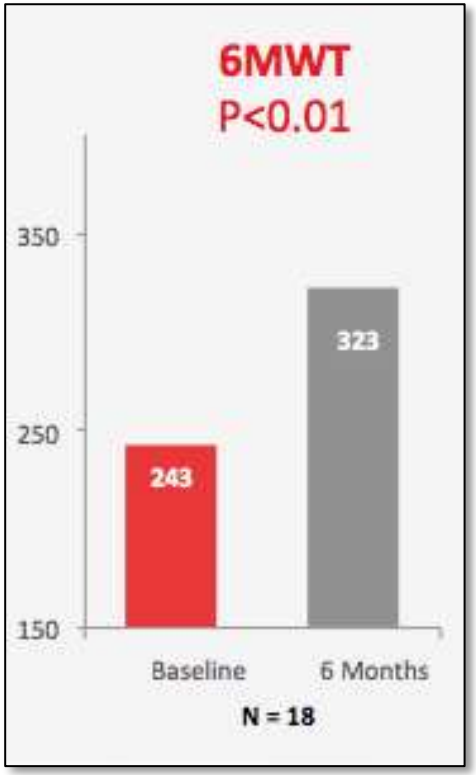
Update from European CARDIOBAND Trial

35 patients results 2/3/2015







24/33 Patients with MR ≤Mild at 6 Months FU

Mean Age 72 (56-81)

STS Repair 7 (1-34)

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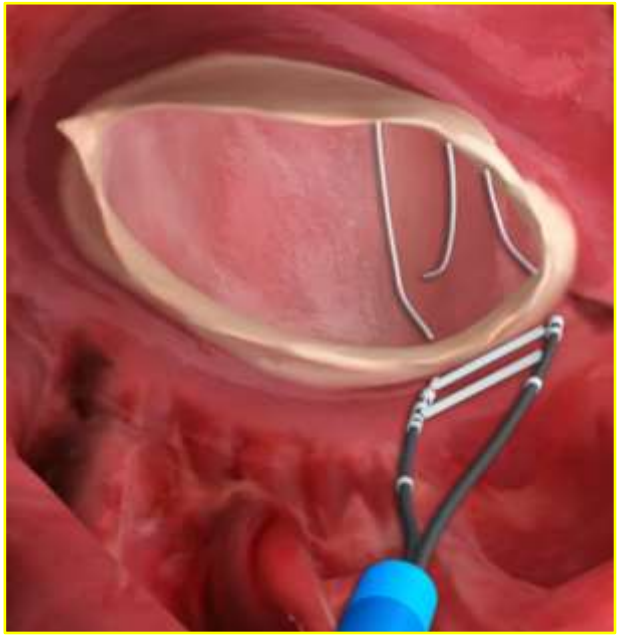
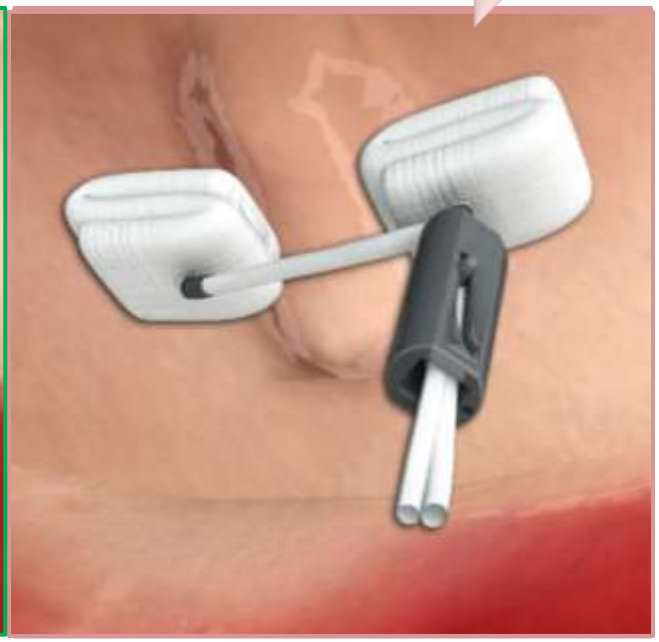
DIRECT ANNULOPLASTY
Mitralign Procedure Steps

Wire Delivery

Pledget Delivery

Plication & Lock





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CE Mark Study

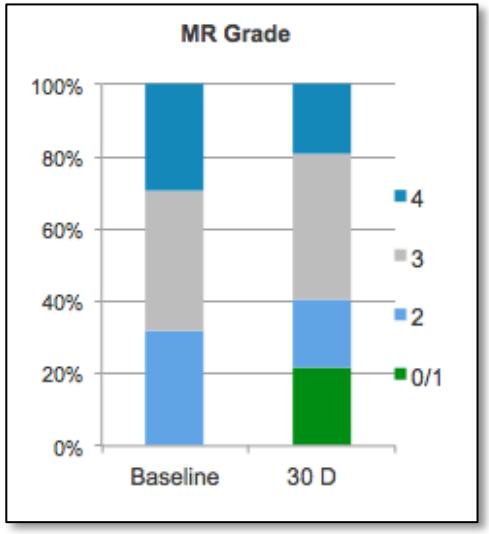
30-Day Performance: Core Lab Adjudicated

Ventricular Changes

	Baseline (n)	30 Day (n)	30 Day Change Paired (n)	30 Day Change P-Value
LVIDd (cm)	6.35 (44)	6.10 (38)	**-0.21 (36)**	**0.004**
LVIDs (cm)	5.37 (44)	5.15 (38)	**-0.21 (35)**	**0.079**
LVEDv (ml)	186.4 (44)	169.0 (38)	**-20.1 (31)**	**< 0.001**
LVESv (ml)	122.8 (44)	110.5 (38)	**-13.1 (31)**	**0.008**

Annular Changes

	Baseline (n)	30 Day (n)	30 Day Paired Change (n)	P-Value
A-P Dia. (cm)	3.58 (44)	3.27 (38)	**-0.39 (31)**	**< 0.001**
S-L Dia. (cm)	3.55 (44)	3.34 (38)	**-0.26 (33)**	**< 0.001**



N=64

Investigational Device Only: Not Available in the EU or US

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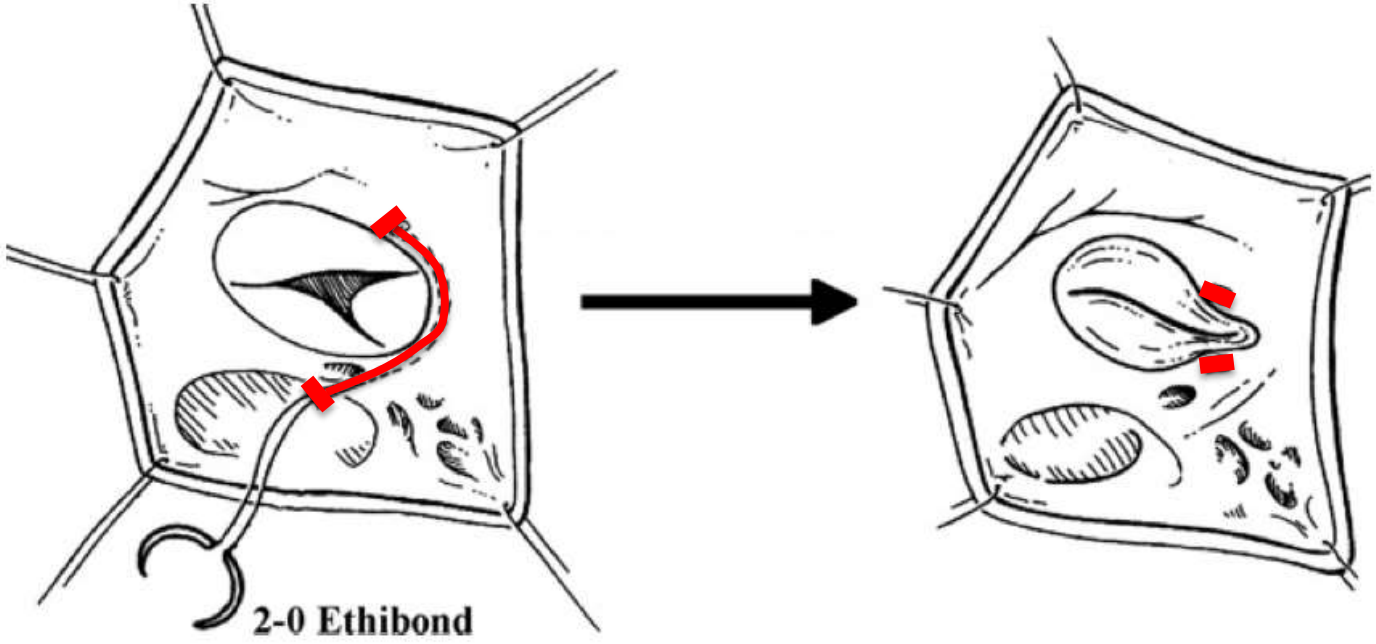
Suture bicuspidization of the tricuspid valve vs ring annuloplasty for functional tricuspid regurgitation

Midterm results of 237 consecutive patients



Suture bicuspidization is performed by placement of a 2-0 pledget-supported mattress suture from the antero-posterior to the posteroseptal commissures along the posterior annulus.

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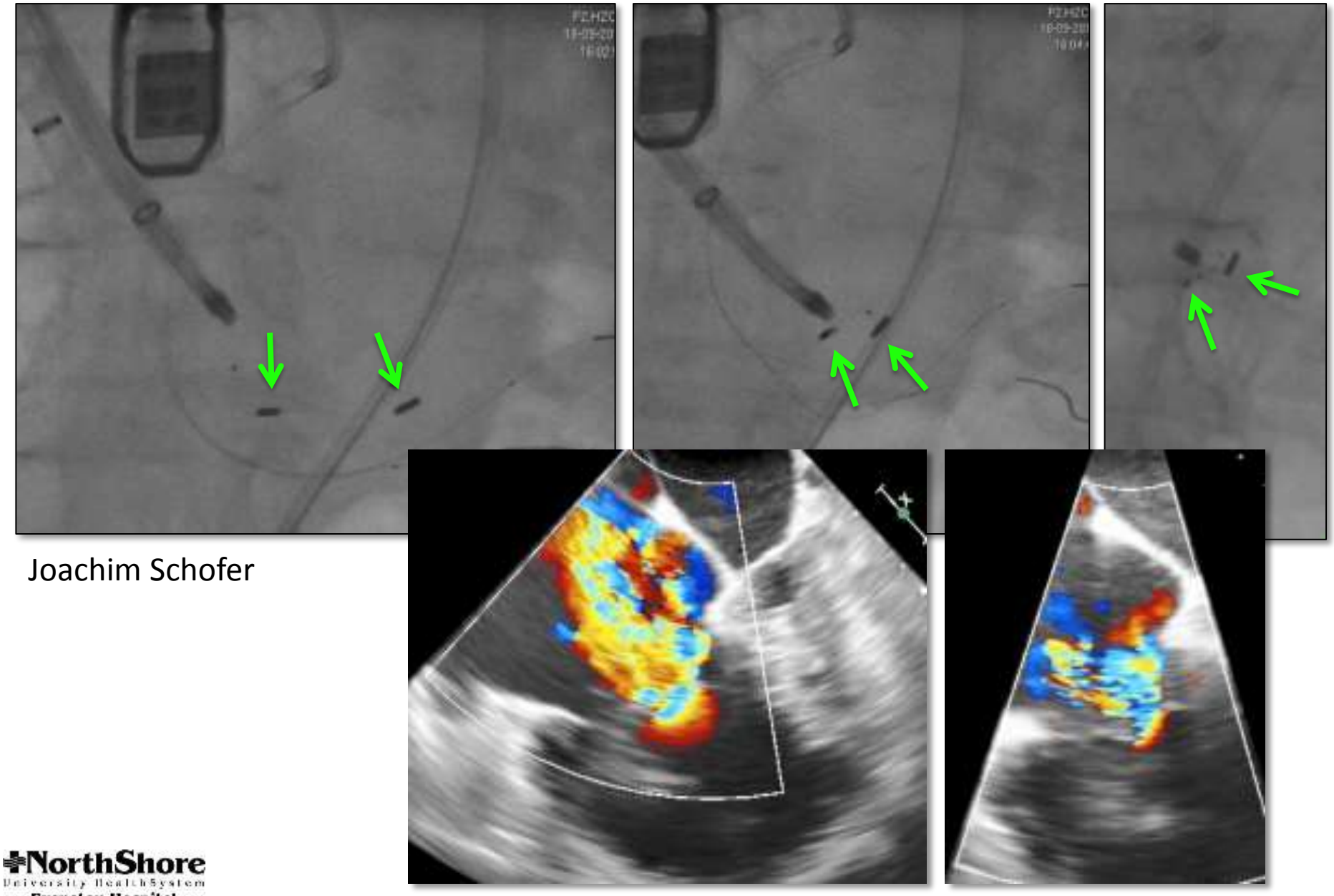
J Thorac Cardiovasc Surg 2007;133:117-126

First Human Report on Percutaneous Repair for Functional Tricuspid Regurgitation with the Mitralign System



Joachim Schofer

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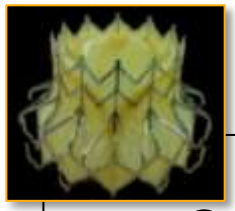
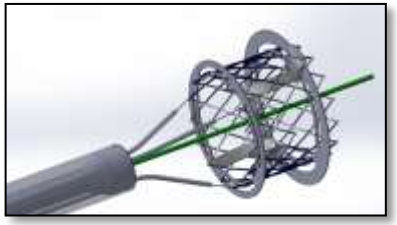
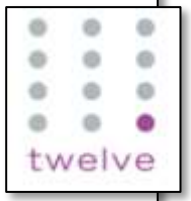
Mitral Replacement Technologies

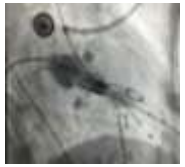


- CardiaAQ
- Neovasc TIARA
- Tendyne
- Edwards FORTIS
- Endovalve
- M-Valve
- Medtronic

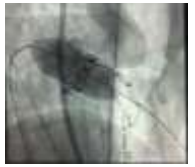


- Valtech
- Lutter
- MitrAssist
- Caisson
- MitraSeal
- Twelve
- HighLife
- Others….





The MITRAL Trial



Mitral **I**mplantation of **TRA**nscatheter va**L**ves in native mitral stenosis

The safety and feasibility of the SAPIEN XT TM Transcatheter Heart Valve with NovaFlex and Ascendra delivery systems in patients with symptomatic severe calcific mitral stenosis who are not candidates for mitral valve Surgery

- Cedars-Sinai Medical Center (Co- Principal Investigators: Saibal Kar, MD; Rajendra Makkar, MD)
- Columbia University (Co-Principal investigators: Susheel Kodali, MD; Martin Leon, MD)
- Evanston Hospital (Co- Principal Investigators: Mayra Guerrero, MD; Ted Feldman, MD)
- Henry Ford Hospital (Principal investigator: William O'Neill, MD)
- Massachusetts General Hospital (Principal Investigator: Igor Palacios, MD)
- Mayo Clinic (Principal Investigator: Charanjit RIhal, MD)

Principal Investigator Mayra Guerrero, MD

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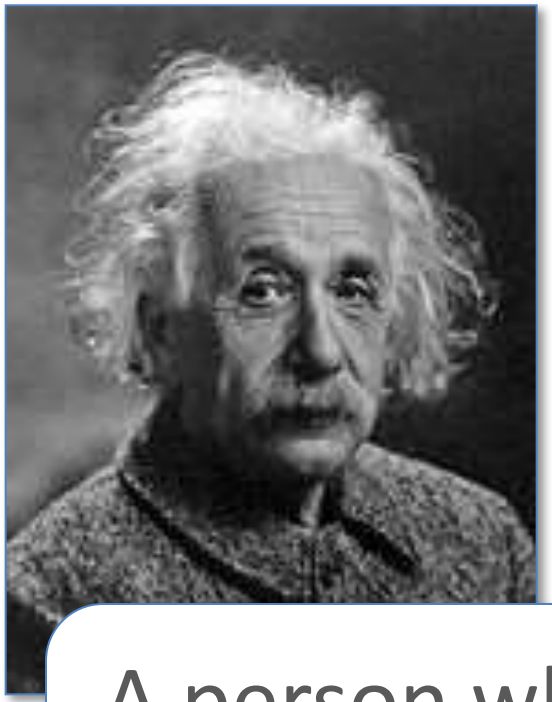

A person who never made a mistake never tried anything new.